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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/017,834	10/30/2001	Martin A. Voet	17341CIP2(BOT)	6724

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Stephen Donovan
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EXAMINER	
KAM, CHIH MIN	
ART UNIT	PAPER NUMBER
1653	

DATE MAILED: 08/25/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/017,834	VOET ET AL.	
	Examiner	Art Unit	
	Chih-Min Kam	1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

P riod for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-13 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-13 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 10-01 .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Claim Rejections-Statutory Basis Double Patenting

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

1. Claims 1, 5, 6 and 9-12 are rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1-3 and 6-9 of prior U.S. Patent No. 6,358,513 because both sets of claims are directed to a method of treating Hashimoto's thyroiditis and have identical scope. This is a double patenting rejection.

Claim Rejections-Obviousness Type Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

2. Claims 1-13 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-7 of U. S. Patent 6,585,970. Although the

conflicting claims are not identical, they are not patentably distinct from each other because claims 1-13 in the instant application disclose a method for Hashimoto's thyroiditis, the method comprising local administration of a therapeutically effective amount of a botulinum toxin to a patient, wherein the botulinum toxin is administered in an amount between 1 unit and 20,000 units effective to ameliorate severity of Hashimoto's thyroiditis between two to six months. This is obvious in view of claims 1-7 in the patent which disclose a method for treating hypothyroidism, the method comprising the administration of a therapeutically effective amount of a botulinum toxin to a thyroid or to a sympathetic ganglion which innervates a thyroid cell of a patient, thereby treating hypothyroidism by alleviating a symptom of hypothyroidism. Both sets of claims cite a method of treating hypothyroidism comprising local administration of an amount of a botulinum toxin effective to ameliorate severity of hypothyroidism of a patient. Thus, claims 1-13 in present application and claims 1-7 in the patent are obvious variations of a method of treating hypothyroidism by local administration of a therapeutically effective amount of a botulinum toxin to a patient, thereby ameliorating severity of hypothyroidism.

3. Claims 1-13 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 2, 4-8, 16 and 17 of U. S. Patent 6,524,580. Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 1-13 in the instant application disclose a method for Hashimoto's thyroiditis, the method comprising local administration of a therapeutically effective amount of a botulinum toxin to a patient, wherein the botulinum toxin is administered in an amount between 1 unit and 20,000 units effective to ameliorate severity of Hashimoto's thyroiditis between two to six months. This is obvious in view of claims 1, 2, 4-8, 16 and 17 in the patent which disclose a

method for treating a thyroid disorder, the method comprising injecting a therapeutically effective amount of a botulinum toxin to a thyroid or to a sympathetic ganglion which innervates the thyroid of a patient, thereby treating a thyroid disorder by influencing a secretion of a thyroid hormone. Both sets of claims cite a method of treating a thyroid disorder such as hypothyroidism by administration of a therapeutically effective amount of a botulinum toxin to the thyroid of a patient. Thus, claims 1-13 in present application and claims 1, 2, 4-8, 16 and 17 in the patent are obvious variations of a method of treating hypothyroidism by local administration of a therapeutically effective amount of a botulinum toxin to a patient, thereby ameliorating severity of hypothyroidism.

4. Claims 1-13 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-11 of co-pending application 10/099,238. Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 1-13 in the instant application disclose a method for Hashimoto's thyroiditis, the method comprising local administration of a therapeutically effective amount of a botulinum toxin to a patient, wherein the botulinum toxin is administered in an amount between 1 unit and 20,000 units effective to ameliorate severity of Hashimoto's thyroiditis between two to six months. This is obvious in view of claims 1-11 of the co-pending application which disclose a method for treating Hashimoto's thyroiditis, the method comprising local administration of a therapeutically effective amount of a clostridial toxin to a patient, thereby treating Hashimoto's thyroiditis. Both sets of claims cite a method of treating Hashimoto's thyroiditis by administering a therapeutically effective amount of a clostridial toxin such as a botulinum toxin to the thyroid of a patient. Thus, claims 1-13 in present application

and claims 1-11 in the co-pending application are obvious variations of a method of treating Hashimoto's thyroiditis by local administration of a therapeutically effective amount of a botulinum toxin to a patient, thereby ameliorating severity of hypothyroidism.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claim 8 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 8 recites the limitation "between about 1 unit and about 100 units" in line 3. There is insufficient antecedent basis for this limitation in claim 1, which cites the amount of a botulinum toxin is between 1 unit and 20,000 units, not the amount below 1 unit as to "about 1 unit". Note that the about expands the bounds of the dependent claim rather than more narrowly defining same.

Conclusion

6. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (703) 308-9437. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low, Ph. D. can be reached on (703) 308-2923. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-0294 for regular communications and (703) 308-4227 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Chih-Min Kam, Ph. D. CMK
Patent Examiner

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August 19, 2003

CHRISTOPHER S. F. LOW
SUPERVISORY PATENT EXAMINER
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